

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

P-2040-US

U.S. APPLICATION NO. 09/7831944

INTERNATIONAL APPLICATION NO.

PCT/IL99/00613

INTERNATIONAL FILING DATE

15 NOVEMBER 1999

PRIORITY DATE CLAIMED

16 NOVEMBER 1998

TITLE OF INVENTION A SENSOR FOR RADIANCE BASED DIAGNOSTICS

APPLICANT(S) FOR DO/EO/US SARUSSI, Israel

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to promptly begin national examination procedures (35 U.S.C. 371(f)).
4. ☐ The US has been elected by the expiration of 19 months from the priority date (PCT Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☒ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A **FIRST** preliminary amendment.
☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☒ Other items or information: 1) Postcard

09/831944

INTERNATIONAL APPLICATION NO.
PCT/IL99/00613

ATTORNEY'S DOCKET NUMBER
P-2040-US

☒ The following fees are submitted:

BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5):
 Neither international preliminary examination fee (37 CFR 1.482)
 nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO
 and International Search Report not prepared by the EPO or JPO \$1000.00
 International preliminary examination fee (37 CFR 1.482) not paid to
 USPTO but International Search Report prepared by the EPO or JPO \$860.00
 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but
 international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$710.00
 International preliminary examination fee paid to USPTO (37 CFR 1.482)
 but all claims did not satisfy provisions of PCT Article 33(1)-(4) \$690.00
 International preliminary examination fee paid to USPTO (37 CFR 1.482)
 and all claims satisfied provisions of PCT Article 33(1)-(4) \$100.00

JC18 Rec'd PCT/PTO 1 6 MAY 2001

CALCULATIONS PTO USE ONLY

ENTER APPROPRIATE BASIC FEE AMOUNT =

\$ 690.00

Surcharge of \$130.00 for furnishing the oath or declaration later than ☐ 20 ☐ 30
 months from the earliest claimed priority date (37 CFR 1.492(e)).

\$

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE
Total claims	32 - 20 =	12	X \$18.00
Independent claims	- 3 =		X \$80.00
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$270.00

\$ 216.00

\$

\$

TOTAL OF ABOVE CALCULATIONS =

\$ 906.00

☐ Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above
 are reduced by 1/2.

\$

SUBTOTAL =

\$ 906.00

Processing fee of \$130.00 for furnishing the English translation later than ☐ 20 ☐ 30
 months from the earliest claimed priority date (37 CFR 1.492(f)).

\$

TOTAL NATIONAL FEE =

\$

Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be
 accompanied by an appropriate cover sheet (37 CFR 3.23, 3.31). \$40.00 per property +

\$

TOTAL FEES ENCLOSED =

\$ 906.00

**Amount to be
 refunded:**

\$ 906.00

charged:

\$

- a. ☐ A check in the amount of \$_____ to cover the above fees is enclosed.
- b. ☒ Please charge my Deposit Account No. 05-0649 in the amount of \$906.00 to cover the above fees.
 A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any
 overpayment to Deposit Account No. 05-0649. A duplicate copy of this sheet is enclosed.

Note: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR
 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

EITAN, PEARL, LATZER & COHEN-ZEDEK

One Crystal Park, Suite 210
 2011 Crystal Drive
 Arlington, VA 22202-3709

Tel: (703) 486-0600 Fax: (703) 487-0800

SIGNATURE:

Mark S. Cohen

NAME

42,425

REGISTRATION NUMBER

A SENSOR FOR RADIANCE BASED DIAGNOSTICS

FIELD OF THE INVENTION

The present invention relates to a sensor and system for radiance based
5 diagnostics of body tissues and to a method for radiance based diagnostics of
body tissues.

BACKGROUND OF THE INVENTION

Radiance based diagnostics of body tissues involves radiating a body
tissue and obtaining data relating to the transmittance or reflection of the radiated
10 light from the tissue, for analysis of tissue constituents. For example,
electro-optical measurement of blood characteristics has been found to be useful
in many areas of blood constituent diagnostics, such as glucose levels, oxygen
saturation, hematocrit, bilirubin and others. Pulse oximetry is a method for
measuring oxygen saturation in the blood, in which two or more wavelengths are
15 radiated through an organ at a point where blood perfuses the organ. Reflective
pulse oximetry employs at least one light source and at least one detector which
are placed at the same side of an organ. The light source is for radiating the organ
and the detector is for receiving the light reflected from the organ. The reflected
light is analyzed for measuring the percent of saturated oxygen in the blood.

20 These methods of body tissue diagnostics usually employ sensors,
which are placed on body tissues, and which comprise at least one radiance
source for radiating the tissue and at least one radiance detector, for detecting the
rays transmitted through or reflected from the tissue. The accuracy of the results

obtained in these methods depends, to a great extent, on ensuring that the detector, or detectors, are exposed only to rays which have passed through the examined tissue and not to other rays, such as rays coming directly from the radiance source.

5 When a sensor is placed on body tissues, especially on stretched tissues (such as over a bone), or due to irregular tissue surface (such as in wrinkles), there might be a small space between the face of the sensor and the tissue, through which some of the rays can pass directly from the radiance source to the detector, thereby adversely affecting the measurement.

10 Reference is now made to Fig. 1 which is a schematic side view illustration of a prior art sensor. The sensor, generally referenced 10, contains a light source 12 and a light detector 14. The sensor is placed onto examined tissue 16 and, when operated, light is radiated from light source 12 onto tissue 16. Depending on how the light source 12 is directed, most of the light will pass
15 through the tissue 16 and be partly reflected from the tissue. The reflected light 14' will be received by detector 14 to be analyzed. However, a small fraction of the light 18' radiated from the light source 12 will not pass through the tissue 16 but pass directly to the detector 14, through the small space 18 between the sensor
20 lights, 14' and 18', the analysis results will be inaccurate.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a sensor for radiance based diagnostics of body tissues, which ensures that only light which has passed through an examined tissue is received by the sensor's detector.

5 The sensor, which is placed on an examined tissue, comprises a performing component and an adhering component. The performing component, which consists of at least one radiance source for radiating a tissue and at least one detector for detecting the rays transmitted through or reflected from the tissue, protrudes from the plane of the adhering component, in the direction of the
10 examined tissue, when being placed on the tissue. The adhering component is capable of fastening the performing component to the examined tissue. The adhering component may be a tape of any suitable adhering material, which forms a frame around the performing component or, the adhering component may be a tape which overlays the performing component, and which, when being
15 fastened to an examined tissue, covers the performing component, fastening it to the underlying tissue.

The design of the sensor, as described above, ensures that, when the adhering component is placed in contact with the tissue, the performing component presses into the tissue in such a way that the radiance source and
20 detector are sealed off from each other by the tissue, thus, when the sensor is operated, only rays from the radiance source, which have passed through the examined tissue, will be received by the detector.

In one embodiment of the invention, especially useful for reflective oximetry, the performing component further comprises a raised partition in

between the radiance source and the detector, or a wall surrounding either the radiance source or the detector, or both, while separating them from each other. The partition or wall assist in sealing off the detector from the radiance source, to further ensure that no light is received by the detector, directly from the radiance source.

In another embodiment, the sensor includes a controlling device which senses external conditions and which is capable of responding to the sensed conditions, such as by arresting the sensor operation when the external conditions indicate inaccurate operation of the sensor. For example, the controlling device may be a pressure or proximity detector that will enable sensor operation only when it senses the required proximity to the examined tissue or a pressure which indicates that the performing component is sufficiently pressed on to the examined tissue.

It is further an object of the present invention to provide a system for radiance based diagnostics of body tissues. The system comprises a sensor and a microprocessor that is in electronic communication with a component of the sensor.

The sensor comprises a performing component consisting of at least one radiance source for radiating a tissue and at least one detector for detecting the rays transmitted through or reflected from the tissue, and an adhering component that is capable of fastening the performing component to an examined body tissue. The microprocessor is in electronic communication with the performing component of the sensor for controlling the radiance source and the detector, and for performing analysis of the data received by the detector.

The sensor may also comprise a controlling device that senses external conditions. The controlling device may be in communication with the microprocessor, providing information to the microprocessor which contributes to its operation of controlling the radiance source and detector. Alternatively, the
5 controlling device may be in direct communication with the radiance source and/or detector, for controlling their operation in accordance with the sensed external conditions.

It is another object of the present invention to provide a method for radiance based analysis of body tissues. The method comprises the steps of
10 fastening the sensor of the invention to an examined tissue, operating the sensor and obtaining data from the sensor.

BRIEF DESCRIPTION OF THE FIGURES

The present invention will be understood and appreciated more fully from the following detailed description taken in conjunction with the drawings in which:

5 Fig. 1 is a schematic side view of a prior art sensor;

 Figs. 2A and 2B are schematic under views of the sensor according to two embodiments of the present invention;

 Fig. 2C is a schematic side view of the sensor according to another embodiment of the present invention.

10 Figs. 3A and 3B are schematic side views of the sensors of Figs. 2A and 2B, respectively, operable according to an embodiment of the present invention;

 Figs. 4A and 4B are schematic under views of the sensors of Figs 2A and 2B, respectively, according to another embodiment of the present invention; and

15 Figs. 5A and 5B are block diagram illustrations of the operation of a system including the sensors of Figs. 2A and 2B and the sensor of Fig 2C, correspondingly.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to a sensor for radiance based diagnostics of body tissues, which ensures that only light from a radiance source, which has
5 passed through an examined tissue, is received by the sensor's detector, thereby ensuring higher accuracy of results.

The invention will be described in reference to reflective pulse oximetry, but it will be appreciated by persons skilled in the art, that the invention relates to any radiance based method of diagnosing body tissues, reflective or other. The
10 radiance source and detector, may, therefore, be situated on the same side of the examined tissue or on opposing sides, according to the diagnostic method used. The terms "radiance source" and "detector", in the present invention, relate to one or more radiance source or detector. Furthermore, the term "radiance source", in the present invention, refers to a radiance source which is not limited to visible
15 light but may radiate in any wavelength which is suitable for the specific method used.

Reference is now made to Figs. 2A, 2B and 2C, which are schematic under views (Fig. 2A and 2B) and side view (Fig. 2C) of a sensor, generally
20 referenced 20. The sensor 20 comprises a performing component 21 and an adhering component 23. The performing component 21 consists of a radiance source 22 for radiating a tissue and detector 24 for detecting the rays reflected from the tissue. The whole performing component 21, or parts of it (such as the radiance source 22 and/or detector 24), protrude from the plane of the adhering component 23.

The adhering component 23 is a tape for fastening the performing component to an examined body tissue, and for keeping it in place. In Figs. 2A and 2C, the adhering component 23 is an adhesive tape forming a frame around the performing component 21, which contacts both the performing component
5 and underlying tissue.. In Fig. 2B the adhering component 23 is a tape, i.e. made of stretchable material, which overlays the performing component, and which, when being fastened to a body tissue, covers the performing component, fastening it to the underlying tissue. The adhering component 23 may be disposable. It will be appreciated that the adhering component may also be
10 formed as part of the performing component such as a band of adhesive material formed on the surface of the performing component meant to contact and adhere to the examined tissue.

The performing component 21 may be powered through a cable 26 (shown only in Fig. 2B). Alternatively, the sensor 20 may be wireless and operated
15 on a battery.

The embodiment described in Fig 2C further comprises a controlling device 126 that may be in communication with either detector 24 or radiance source 22 or both. Controlling device 126 is capable of sensing external conditions and responding to these conditions. A detailed description of controlling
20 device 126 is provided in the description of Fig. 5B.

Reference is now made to Figs. 3A and 3B which are schematic side view illustrations of a sensor operable according to the invention. When the sensor, generally referenced 30, is placed on a body tissue 35, such that the adhering component 33 is placed in contact with the tissue 35, the performing

component 31, which protrudes from the plane of the adhering component 33, in the direction of the tissue 35, presses into the tissue 35, forming indentation 35'. Adhering component 33 is in contact with performing component 31, such that, the adhering component surface 33' is essentially parallel to the performing component surface 31'. Accordingly, when sensor 30 is fastened to tissue 35, there is essentially no space between the adhering component 33, and the tissue 35. This ensures that the performing component 31 is pressed onto tissue 35 such that light cannot reach the detector either from the outside or directly from the radiance source.

The pressure exerted by performing component 31 on the tissue, fastens the radiance source and detector (not shown) to the tissue so that rays emitted from the radiance source, are unable to reach the detector through any other medium, but the tissue.

The performing component surface 31' can be coated or overlaid with a soft layer, such as a silicone or sponge layer. The soft layer, which does not overlay the radiance source or detector, will contribute to sealing off of the radiance source from the detector when the sensor is pressed onto the tissue 35.

Reference is now made to Figs 4A and 4B which are schematic under view illustrations of a sensor, generally referenced 40, according to another embodiment of the invention. In this embodiment, which is especially suitable for use in reflective oximetry, the performing component 41 of the sensor 40 comprises a raised partition 46 in between the radiance source 42 and the detector 44. The sensor 40 may also comprise a wall 46' surrounding either the radiance source 42 or the detector 44, or both, while separating them from each

other (shown in Fig. 4B). When sensor 40 is fastened to a body tissue (as described in Figs. 3A and 3B) by adhering component 43, partition 46 or wall 46', which are raised above the plane of the sensor 40, exert pressure on the tissue and thus seal off the detector 44 from the radiance source 42.

5 Reference is now made to Fig 5A, which is a block diagram illustration of the operation of a system for radiance based diagnostics of body tissues, which includes the sensors 20 of Figs. 2A and 2B. The system comprises an electronic circuit i.e., microprocessor 130 that is in electronic communication with the performing component of sensor 20 which includes radiance source 132 and
10 detector 134. Microprocessor 130 controls radiance source 132 and/or detector 134 operation. Detector 134 provides microprocessor 130 with data relating to the light detected by it. Microprocessor 130 performs data analysis 138 which may include saving the data and/or further processing it and, optionally, displaying the processed data. Data analysis 138 may be performed in the same physical unit of
15 microprocessor 130 or in a separate unit which is in communication with microprocessor 130. The processed data may further effect microprocessor 130 operation. Thus the microprocessor 130 operation may be fine tuned in accordance with the conditions prevailing in the examined tissue, as they are interpreted by the data analysis function of the microprocessor.

20 It will be appreciated that the term "microprocessor" relates to an electronic circuit capable of communicating with and/or controlling sensor components as described.

Fig 5B is a block diagram illustration of a system for radiance based diagnostics of body tissues, that includes the sensor 20 of Fig. 2C. This sensor

includes controlling device 136 that may be in communication with microprocessor 130, on one hand and with radiance source 132 and detector 134, on the other hand, and through which microprocessor 130 may control radiance source 132 and detector 134 operation.

5 Controlling device 136 responds to external conditions, such as external pressure or external temperature, and may inform microprocessor 130 of these conditions. Microprocessor 130 may be programmed to differentially operate according to different external conditions. For example, controlling device 136 may function to alert microprocessor 130 of the fact that there is insufficient
10 pressure or proximity to the examined tissue, and according to the programmed parameters, microprocessor 130 may either stop sensor 20 operation, or alert an operator by displaying this fact, through data analysis 138.

Alternatively, controlling device 136 may be a switch which responds to pressure or proximity to the examined tissue 35 (see Figs. 3A and 3B). Thus,
15 when the performing component 21, or parts of it, are sufficiently pressed to examined tissue 35, so as to ensure that only light from radiance source 132 that has passed through the examined tissue 35, will be detected by detector 134, the controlling device 136 will be in the ON indication, either enabling microprocessor 130 operation or enabling communication between the
20 microprocessor 130 and radiance source 132 and detector. When insufficient pressure or proximity, between the performing component and the examined tissue, is detected by controlling device 136, it will be in the OFF indication, thereby either arresting microprocessor 130 operation or disconnecting the communication between the microprocessor 130 and radiance source 132 and

detector 134. Thus the controlling device 136 contributes to the sensor 20 efficiency.

The controlling device 136 may also respond to other external parameters, such as the examined tissue temperature. Thus, the controlling device 136 will either alert an operator, disconnect the microprocessor or disconnect communication between the microprocessor and the performing component, if it senses a temperature different from that of a preprogrammed temperature, such as the body temperature. The sensor 20, which may need to be placed on the examined tissue 35 for a long period, such as over night, may heedlessly fall off the examined tissue 35 and be pressed on to the patient's bed, instead of onto his body. The microprocessor 130 will be alerted to this fact by the controlling device 136, and act accordingly, as described above.

The controlling device 136 may additionally function to ensure that the microprocessor 130 is operative only with the appropriate sensor 20. For example, sensor 20 can include a controlling device 136 that is a pressure detector that is in the OFF indication for the time it takes to achieve appropriate pressure between the sensor and the examined tissue. Accordingly, microprocessor 130 can be programmed to operate only after being shut off for a predetermined period (which would be, for example, the time it takes to achieve appropriate pressure between the sensor and examined tissue). Thus, a sensor 20 that does not include a controlling device 136 will not be operative with the programmed microprocessor 130.

Both in Fig 5A and in Fig 5B, the microprocessor 130 control of the sensor 20 components (radiance source 132 and/or detector 134) may be

achieved through connecting wires or by remote control, such as by utilizing radiant energy. Thus the microprocessor 130 may be in close contact with the sensor 20, situated close to the patient's body, or the microprocessor 130 may be at some distance from the sensor 20.

5

It will be appreciated by persons skilled in the art that the present invention is not limited by what has been particularly shown and described herein above. Rather the scope of the invention is defined by the claims which follow:

1. A method of monitoring a patient's vital signs, comprising the steps of:
a) providing a sensor for monitoring a patient's vital signs;
b) providing a microprocessor for processing the signals from the sensor;
c) providing a display for displaying the processed signals;
d) providing a power source for the sensor, microprocessor and display;
e) providing a means for connecting the sensor, microprocessor and display to the power source;
f) providing a means for connecting the sensor, microprocessor and display to the display;
g) providing a means for connecting the sensor, microprocessor and display to the power source;
h) providing a means for connecting the sensor, microprocessor and display to the display;
i) providing a means for connecting the sensor, microprocessor and display to the power source;
j) providing a means for connecting the sensor, microprocessor and display to the display;
k) providing a means for connecting the sensor, microprocessor and display to the power source;
l) providing a means for connecting the sensor, microprocessor and display to the display;
m) providing a means for connecting the sensor, microprocessor and display to the power source;
n) providing a means for connecting the sensor, microprocessor and display to the display;
o) providing a means for connecting the sensor, microprocessor and display to the power source;
p) providing a means for connecting the sensor, microprocessor and display to the display;
q) providing a means for connecting the sensor, microprocessor and display to the power source;
r) providing a means for connecting the sensor, microprocessor and display to the display;
s) providing a means for connecting the sensor, microprocessor and display to the power source;
t) providing a means for connecting the sensor, microprocessor and display to the display;
u) providing a means for connecting the sensor, microprocessor and display to the power source;
v) providing a means for connecting the sensor, microprocessor and display to the display;
w) providing a means for connecting the sensor, microprocessor and display to the power source;
x) providing a means for connecting the sensor, microprocessor and display to the display;
y) providing a means for connecting the sensor, microprocessor and display to the power source;
z) providing a means for connecting the sensor, microprocessor and display to the display;

CLAIMS

1. A sensor, for radiance based diagnostics, comprising

a performing component and an adhering component

said performing component comprising at least one radiance
5 source for radiating a tissue and at least one detector for detecting
rays emitted from said radiance source, and

said adhering component being capable of fastening the
performing component to a tissue such that the radiance source and
detector are facing and contiguous with the tissue,

10 wherein, when operative, the adhering component fastens the
performing component to the tissue to the extent that the detector
receives only rays which are transmitted through or reflected from the
tissue.

2. A sensor according to claim 1 wherein the adhering component is a tape
15 of adhering material framing the performing component and which, when
fastening the performing component to the tissue, contacts the tissue.
3. A sensor according to claim 1 wherein the adhering component is a tape
which, when fastening the performing component to the tissue, overlays
the performing component and contacts the tissue.
- 20 4. A sensor according to claim 1 wherein the adhering component is formed
as part of the performing component and contacts both the performing

component and the tissue.

5. A sensor according to claim 1 wherein the performing component further comprises a partition in between the radiance source and the detector.

6. A sensor according to claim 5 wherein the partition further surrounds
5 either radiance source or detector or both.

7. A sensor according to claim 1 wherein the performing component has a performing component surface which faces the tissue, and the adhering component has an adhering component surface which faces the tissue and wherein the performing component surface protrudes from the plane
10 of the adhering component surface in the direction of the tissue.

8. A sensor according to claim 7 wherein the performing component further comprises a partition in between the radiance source and the detector.

9. A sensor according to claim 8 wherein the partition further surrounds either radiance source or detector or both.

10. A sensor according to claim 1 further comprising a controlling device capable of sensing and responding to external conditions and capable of controlling sensor components operation.

11. A sensor according to claim 10 wherein the controlling device is a pressure or proximity detector which enables sensor operation when the
20 performing component is fastened to the tissue to the extent that the detector receives only rays which are transmitted through or reflected

from the tissue.

12. A sensor according to claim 7 further comprising a controlling device capable of sensing and responding to external conditions and capable of controlling the sensor components operation.

5 13. A system for radiance based diagnostics comprising a sensor and an electronic circuit that is in communication with the sensor components and is capable of controlling the sensor components operation wherein

the sensor comprises a performing component and an adhering component

10 said performing component comprising at least one radiance source for radiating a tissue and at least one detector for detecting rays emitted from said radiance source, and

15 said adhering component being capable of fastening the performing component to a tissue such that the radiance source and detector are facing and contiguous with the tissue,

wherein, the adhering component fastens the performing component to the tissue to the extent that the detector receives only rays which are transmitted through or reflected from the tissue.

20 14. A system according to claim 13 wherein the electronic circuit is in communication with and is capable of controlling the operation of either radiance source or detector or both.

15. A system according to claim 13 wherein the adhering component is a

tape of adhering material framing the performing component and which, when fastening the performing component to the tissue, contacts the tissue.

16. A system according to claim 13 wherein the adhering component is a
5 tape which, when fastening the performing component to the tissue, overlays the performing component and contacts the tissue.

17. A system according to claim 13 wherein the performing component further comprises a partition in between the radiance source and the
10 detector.

18. A system according to claim 17 wherein the partition further surrounds either radiance source or detector or both.

19. A system according to claim 13 wherein the performing component has a performing component surface which faces the tissue, and the adhering
15 component has an adhering component surface which faces the tissue and wherein the performing component surface protrudes from the plane of the adhering component surface in the direction of the tissue.

20. A system according to claim 17 wherein the performing component further comprises a partition in between the radiance source and the
20 detector.

21. A system according to claim 20 wherein the partition further surrounds either radiance source or detector or both.

22. A system according to claim 13 wherein the sensor further comprises a controlling device capable of sensing and responding to external conditions and which controlling device is capable of being in communication with sensor components, electronic circuit or both.
- 5 23. A system according to claim 22 wherein the electronic circuit controls the sensor component's operation.
24. A system according to claim 22 wherein the controlling device is a pressure or proximity detector which enables sensor components operation when the performing component is fastened to the tissue to the extent that the detector receives only rays which are transmitted through or reflected from the tissue.
- 10 25. A system according to claim 22 wherein the controlling device is a pressure or proximity detector which communicates with the electronic circuit to enable sensor components operation when the performing component is fastened to the tissue to the extent that the detector receives only rays which are transmitted through or reflected from the tissue.
- 15 26. A system according to claim 22 wherein the electronic circuit is programmed to operate in accordance with specific conditions communicated by the controlling device.
- 20 27. A method for radiance based analysis of body tissues comprising the steps of

fastening to the body tissue a sensor according to claim 1;
operating the sensor; and
obtaining data from the sensor.

28. A method for radiance based analysis of body tissues comprising the
5 steps of

fastening to the body tissue a system according to claim 13;
operating the system; and
obtaining data from the system.

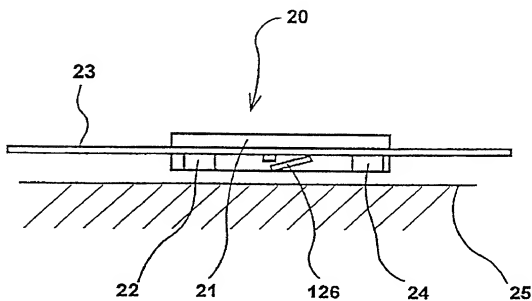
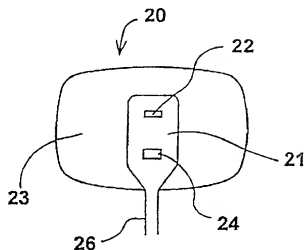
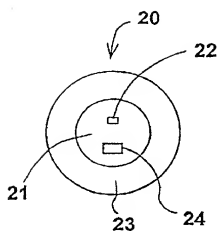
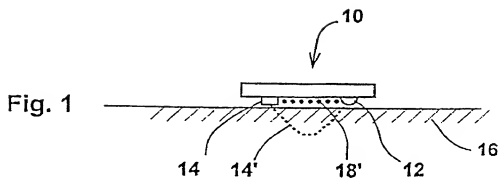
29. Use of a sensor according to claim 1 in radiance based analysis of body
10 tissues.

30. Use according to claim 29 wherein the radiance based analysis is
reflective pulse oximetry .

31. Use of a system according with claim 13 in radiance based analysis of
body tissues.

15 32. Use according to claim 31 wherein the radiance based analysis is
reflective pulse oximetry.

1/3



2/3

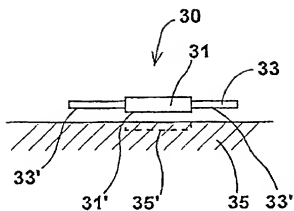


Fig. 3A

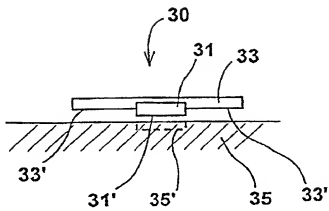


Fig. 3B

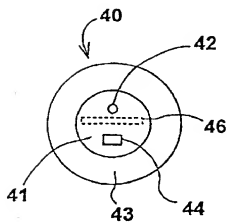


Fig. 4A

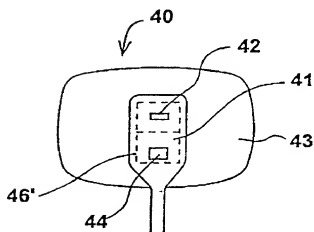


Fig. 4B

3/3

FIG. 5A

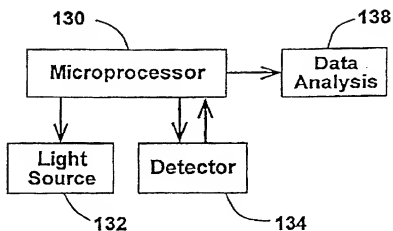
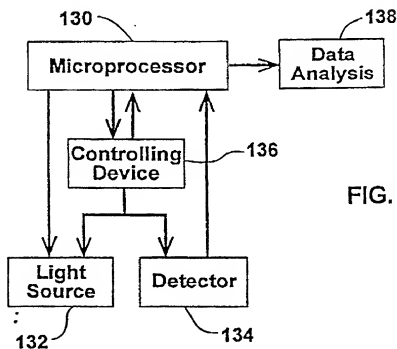


FIG. 5B



DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below under my name.

I believe that I am the original, first and sole inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled

A SENSOR FOR RADIANCE BASED DIAGNOSTICS

the Specification of which



is attached hereto
was filed on **November 15, 1999**
as United States Application Number or PCT International
Application No. **PCT/IL99/00613**
and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified Specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, 1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any provisional application filed in the United States in accordance with 35 U.S.C. §1.119(e), or any application for patent that has been converted to a Provisional Application within one (1) year of its filing date, or any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

PRIOR FILED APPLICATION(S)

<u>APPLICATION NUMBER</u>	<u>COUNTRY</u>	<u>(DAY/MONTH/YEAR FILED)</u>	<u>PRIORITY CLAIMED</u>
PCT/IL/99/00613	PCT	15 NOVEMBER 1999	Yes
60/108,505	US	16 NOVEMBER 1998	
60/113,986	US	28 DECEMBER 1998	

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application listed below, and, insofar as the subject matter of each of the claims of this application is not disclosed in any prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a), which occurred

between the filing date of the prior application and the national or PCT international filing date of this application:

APPLICATION NO.	FILING DATE (DAY/MONTH/YEAR)	STATUS - PATENTED, PENDING, ABANDONED
PCT/IL/99/00613	15 NOVEMBER 1999	Pending
60/108,505	16 NOVEMBER 1998	Expired
60/113,986	28 DECEMBER 1998	Expired

I hereby appoint as my attorney(s) and agent(s) Heidi M. Brun (Agent, Registration No. 35,104), or Daniel J. Swirsky (Agent, Registration No. 45,148) or Mark S. Cohen (Attorney, Registration No. 42,425) or Rochel L. Abboudi (Agent, Registration No. 44,490) or Suzanne Erez (Agent, Registration No. 46,688) or Vladimir Sherman (Attorney, Registration No. 43,116) or David Klein (Agent, Registration No. 41,118) or Adele Marcus (Agent, Registration No. 47,769) said attorney(s) and agent(s) with full power of substitution and revocation to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

Please address all correspondence regarding this application to:

EITAN, PEARL, LATZER, & COHEN-ZEDEK
ONE CRYSTAL PARK, SUITE 210
2011 CRYSTAL DRIVE
ARLINGTON, VA 22202-3709

Direct all telephone calls to (703) 486-0600 and all facsimiles at (703) 486-0800.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

FULL NAME OF INVENTOR: SARUSSI, Israel
 FULL RESIDENCE ADDRESS: Moshav Gane Tal, Mobile Mail Hof Aza 79792, Israel
 COUNTRY OF CITIZENSHIP: Israel
 FULL POST OFFICE ADDRESS: same

SIGNATURE OF INVENTOR X [Signature]

DATE X 6/7/01